



1641 JFW

Attorney Docket No.: 19626-0112 (45454-259755)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:	)	
	)	
<b>Reiko M. Nakamura</b>	)	
	)	Art Unit: <b>1641</b>
Serial No.: <b>09/877,802</b>	)	
	)	Examiner: <b>Gabel, G.</b>
Filed: <b>June 6, 2001</b>	)	
	)	
For: <b>METHODS AND COMPOSITIONS FOR</b>	)	
<b>DETECTION AND DIAGNOSIS OF</b>	)	
<b>INFECTIOUS DISEASES</b>	)	

**OFFICIAL COMMUNICATION**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Further to the Supplemental Preliminary Amendment submitted in the above-identified patent application on October 26, 2004, Applicant submits herewith an original *In re Katz* declaration.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on November 5, 2004.



Sima Singadia Kulkarni – Reg. No. 43,732

## **REMARKS**

The present application is directed to devices and compositions for detecting and diagnosing infectious diseases. In particular, the application relates to the use of a transdermal delivery device to diagnose infectious diseases such as mycobacterial infections.

### ***Declaration***

In the conjunction with the Supplemental Preliminary Amendment submitted in the present application on October 26, 2004, Applicant submitted a facsimile copy of an *In re Katz* declaration pursuant to 37 C.F.R. §1.132 signed by Dr. Reiko Nakamura. Enclosed herewith, is the original version of the declaration bearing the original signature.

### ***Conclusion***

In conclusion, Applicant believes that the claims are in condition for allowance. A Notice of Allowance is therefore respectfully solicited. If the Examiner believes any informalities remain in the application, which may be corrected by Examiner's Amendment, whether any other issues can be resolved by telephone interview, telephone call with the undersigned attorney at (404) 745-2463 is courteously solicited.

Respectfully submitted,



Sima Singadia Kulkarni  
Registration No. 43,732

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Telephone: (404) 745-2463  
Our File: 19626-0112 (45454-259755)



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**DECLARATION UNDER 37 C.F.R. §1.132 BY REIKO M. NAKAMURA**

1. I, Reiko M. Nakamura, Ph.D., the sole inventor of the above-referenced U.S. patent application, do hereby declare that I received a Bachelor of Art degree and a Doctor of Philosophy degree in zoology from Tokyo Kyoiku University in 1958 and 1963, respectively, and currently work as a consultant for Sequella Inc. in the United States.

2. The pending claims of the above-referenced U.S. patent application have been rejected under 35 U.S.C. 102(a) in view of Japanese Patent Application No. JP 09206092. The referenced Japanese patent application lists Katsuhide Kawajiri, Ikuro Honda, Ichiro Toida and me as co-inventors.

3. I declare that Katsuhide Kawajiri, Ikuro Honda, Ichiro Toida did not discover the subject matter claimed in the above-identified U.S. patent application. I am the sole inventor of the subject matter disclosed in the above-identified U.S. patent application. Katsuhide Kawajiri, Ikuro Honda and Ichiro Toida were working in my laboratory at the time the subject matter of the referenced Japanese patent application was being investigated. For the duration of that investigation and pursuant to my supervision and direction, Katsuhide Kawajiri and Ikuro Honda conducted various experiments, which were directed to the isolation of proteins from BCG short culture. Ichiro Toida supported

the investigation as a manager of Japan BCG Laboratory. At no time did Katsuhide Kawajiri, Ikuro Honda or Ichiro Toida make any inventive contribution to the subject matter claimed in the above-referenced patent application.

4. As the person signing below, I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application, or any patent issued thereon.

**Dated:** Oct. 25, 2004

Reiko M. Nakamura

**Name:** Reiko M. Nakamura

**Citizenship:** Japan

**Residence:** Japan

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